ACMI Disposable Bipolar Cord
ACMI Corporation
136 Turnpike Rd.
Southborough, MA 01772

AUG 2 2 2002

510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI DISPOSABLE BIPOLAR CORD

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	9920160
Contact Person:	John A. DeLucia VP, Quality Assurance, Regulatory Affairs and Clinical Affairs
Date Prepared:	July 26, 2002

Device Description

Classification Name:	Endoscope and accessories (21CFR 876.1500) Gynecologic Electrocautery and Accessories (21CFR 884.4120)
Trade Name:	ACMI Disposable Bipolar Cord
Generic/Common Name:	Endoscope and accessories

Predicate Devices

ACMI Disposable Active Cord	Preamendment & K890328

Intended Uses

The Disposable Bipolar Cord connects the electrode that is inserted into the Resectoscope Working Element (WE) to an Electrosurgery unit (ESU). It allows RF power to be conductively transmitted from the ESU to the resectoscope electrode. It is intended to be sold as a sterile, single use disposable device.

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Southborough, MA 01772

Product Description

The ACMI Bipolar Disposable Cord, Catalogue # DBC, interconnects electrosurgical unit (ESU) (source of RF power) to the Electrode that is inserted into the Bipolar Resectoscope Working Element. It allows RF power to be conductively transmitted from the ESU to the resectoscope electrode.

The Bipolar Disposable Cord is a component or accessory of the ACMI Bipolar Resectoscope System. It is sold as a sterile, single use disposable device. The Bipolar Disposable Cord consists of the following:

a. Cord: containing a twisted wire pair that transmits power from the proximal two-pin connector to contacts in the distal molded connector part. The cable is shielded within an outer insulating jacket.

b. Distal Connector: Two "c-spring" contacts with polyurethane over-mold and "T" shaped strain relief. The distal connector contacts the electrode, which is inserted into the Resectoscope Working Element.

c. Proximal Connector: Two-pin (female) connector over-molded with polyvinyl chloride strain relief.

This Special 510(k) proposes a modification in the design, performance, dimensional, and materials specifications for Disposable Bipolar Cord. The indications for use, principles of operation, the packaging materials, and the sterilization parameters of the Disposable Bipolar Cord remain the same as in the predicate device.

Summary of Safety and Effectiveness

The proposed modifications for the Disposable Bipolar Cord, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, dimensional specifications, and materials specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2002

Mr. John A. DeLucia
Vice President, Quality Assurance,
Regulatory Affairs, Clinical Affairs
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K022480
Trade/Device Name: ACMI Disposable Bipolar Cord
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Regulation Number: 21 CFR §884.4120
Regulation Name: Gynecologic electrocautery and accessories
Regulatory Class: II
Product Code: 85 HGI
Dated: July 26, 2002
Received: July 26, 2002

Dear Mr. DeLucia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: ACMI Disposable Bipolar Cord

510(k) Number: K022480

Indications for use:

The Disposable Bipolar Cord connects the electrode that is inserted into the Resectoscope Working Element to an Electrosurgery unit (ESU). It allows RF power to be conductively transmitted from the ESU to the resectoscope electrode. It is intended to be sold as a sterile, single use disposable device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __X__ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022480